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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/463,881 04/18/00 DAVID

W 9267.8

EXAMINER

HM12/0912

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PHILADELPHIA PA 19102

HARTTER, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/463,881

Applicant(s)

David et al.

Examiner

Hartter

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1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Attachment to PTO-948

### **Election/Restriction**

Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore this restriction is made final.

### **Detailed Action**

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claims 1-11 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make /or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re wands, 8 USPQ2d 1400 At 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The first rejection is based on the fact that the Applicant presents a complicated formula for the derivation of fitness that is not well known in the art. The mechanisms that are used to derive the calculations proceeding from the trial studies unto the survival structures is not made clear. Such methods would require undue experimentation by one skilled in the art without specific guidance for the various calculations.

Furthermore, there is no guarantee in the instant Application that the methodology that is employed is that of a convergent nature, as each succeeding set of trial structures is found. Indeed the threshold values that are employed could result in a divergent product selection. Without an adequate definition of the threshold values, the method will not result in a reasonably predictable result convergent. These same issues are present in claims, which are directly or indirectly dependent from claim 1.

Claims 1-11 also recite the limitation of "predetermined threshold" as is stated in Claim 1. There is insufficient enablement for this limitation in the claim. The predetermined threshold is not defined in the specification so as to enable the reader to reproduce it.

Claims 1-11 recite in addition the limitation of a "predetermined unit cell and space group" in Claim 1. These units lack the definition to enable the claims. These same issues are covered within claims 1-11 by claims directly or indirectly dependent from claim 1.

The second basis of rejection applies to claims 1-4 and 6-11. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while

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being enabling, subject to the above lack of enablement rejection regarding the fitness formula in Claim 5, does not reasonably provide enablement for generic fitness calculation as in Claims 1-4 and 6-11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to derive the invention commensurate in scope with these claims.

The issue lies within the fact that only Claim 5 provides the reader with specific information regarding the fitness formula. The other claims address the matter of fitness and incorporate the subject into the claims but no means except that in claim 5 is provided for the specific calculation of fitness.

Claim 5 is additionally rejected due to enablement issues. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim provides the variables for the accomplishment of the formula but the claim does not provide enough information for the deduction of the specific values of these variables. Therefore one skilled in the art could not deduce enough of the variables to accomplish the invention. Claims 1-4 and 6-11 recites the limitation "fitness" in Claim 1. There is insufficient scope of enablement for this limitation in these claims. The specification lacks support in definition for the fitness term beyond that that is presented in Claim 5. The fitness protocol is referred to in several instances and it is not made clear that the formula that is proposed in Claim 5 is the formula that is applied always.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant introduces in Claims 11 the concept of an annealing procedure. The annealing procedure is not regarded in any of the proceeding claims nor is it addressed in the specification. This leads to indefiniteness in the claim due to lack of antecedent basis.

### **Conclusion**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is also hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (rev. 03/01 or earlier)". Due to the above notification Applicants are required to submit drawing corrections within the time period set for responding to this Office Action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to respond to this Office Action.

Any inquiry concerning this communication or earlier communication from this examiner should be directed to Amy Hartter whose telephone number is (703) 305-

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1696. The examiner can normally be reached Monday-Friday from 8:00 to 4:30 p.m.  
(Eastern Time).

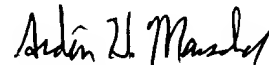
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 305-4028. The fax numbers for the group are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Kim Davis, whose telephone number is (703) 305-3015 or to the Technical Center receptionist whose telephone number is (703) 308-0196.



Amy Hartter

(703) 305-1696



ARDIN H. MARSCHEL  
PRIMARY EXAMINER